

In the Claims

The following listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-32 (Canceled).

33. (Currently Amended) A bi-layer wax-film having a total thickness of less than 5 mm, comprising:

(a) a pH-sensitive mucoadhesive layer[[,]]that is free of any natural polymers and free of any neutral polymers, comprising:

(1) at least one water-insoluble swellable anionic mucoadhesive polymer; and

(2) at least one anionic pH-sensitive film-forming polymer;

(b) a water-insoluble wax layer bonded to the pH-sensitive mucoadhesive layer; and

(c) at least one molecule of interest.

34. (Original) The wax-film composite of claim 33, wherein the pH-sensitive mucoadhesive layer is present at a concentration of 20% to 90% by weight, and the water-insoluble wax layer is present at a concentration of 10% to 80% by weight.

35. (Canceled)

36. (Currently Amended) The wax-film composite of claim [[35]]33, wherein the water-insoluble swellable anionic mucoadhesive polymer is polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol.

37. (Currently Amended) The wax-film composite of claim [[35]]33, wherein the water-insoluble swellable anionic mucoadhesive polymer is Noveon or Carbomer.

38. (Currently Amended) The wax-film composite of claim ~~[[35]]33~~, wherein the water-insoluble swellable anionic mucoadhesive polymer is Noveon ~~and is present in the pH-sensitive mucoadhesive layer at a concentration from 33% to 80% w/w.~~

39. (Currently Amended) The wax-film composite of claim ~~[[35]]33~~, wherein the anionic pH-sensitive film-forming polymer present in the pH-sensitive mucoadhesive layer is a copolymer of methacrylic acid and acrylic or methacrylic ester.

40. (Currently Amended) The wax-film composite of claim ~~[[35]]33~~, wherein the anionic pH-sensitive film-forming polymer is a Eudragit polymer ~~and is present in the pH-sensitive mucoadhesive layer at a concentration from 20% to 67% w/w.~~

41. (Currently Amended) The wax-film composite of claim ~~[[35]]38~~, wherein the anionic pH-sensitive film-forming polymer ~~present in the pH-sensitive mucoadhesive layer is a Eudragit S100. polymer, or chemical derivative thereof.~~

42. (Original) The wax-film composite of claim 33, wherein the water-insoluble wax layer comprises at least one water-insoluble pharmaceutical wax having a melting point between 40° C and 100° C and at least one water-soluble or water-swellaable polymer.

43. (Original) The water-insoluble pharmaceutical wax of claim 42, wherein said wax is DENTSPLY® Utility Wax, beeswax, emulsifying wax, microcrystalline wax, carnauba wax, paraffin wax, white wax, yellow wax, or other suitable pharmaceutical wax.

44. (Previously Presented) The water-soluble or swellable polymer of claim 42, wherein said polymer is present in the insoluble wax layer at a concentration from 0.05% to 10% by weight.

45. (Original) The water-soluble or swellable polymer of claim 42, wherein said water-soluble or water-swellaable polymer is tragacanth, polyvinyl pyrrolidone, polyvinyl alcohol, cross-linked polyacrylic acid, polyethylene glycol, a cellulose polymer derivative, or other suitable pharmaceutical polymer that is water-soluble or water-swellaable.

46. (Currently Amended) The wax-film composite of claim ~~[[35]]~~33, wherein the molecule of interest is contained in and released from either the pH-sensitive mucoadhesive layer or the water-insoluble wax layer.

47. (Currently Amended) The wax-film composite of claim ~~[[35]]~~33, wherein the molecule of interest comprises an active pharmaceutical compound ~~such as an antimicrobial, antiviral, antiinflammatory, antiseptic, antihistimine, a local anesthetic, a disinfectant, a keratolytic, an analgesic, an anti-migrane, anti-fungal, a sweetners~~sweetener, a flavoring agent, a diagnostic agent, or a combination thereof.

48. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is amlexanox.

49. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is triclosan.

50. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is lidocaine, benzocaine, or dyclonine.

51. (Currently Amended) The wax-film composite of claim ~~[[35]]~~33, wherein the molecule of interest is a peptide or protein.

52. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is at least one benzodiazepine drug or derivative thereof.

53. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is hirudin or hirudin complexed with a substance of opposite charge.

54. (Withdrawn) The wax-film composite of claim 53, wherein said substance of opposite charge is chitosan or protamine.

55. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is plasmid DNA or plasmid DNA complexed with a substance of opposite charge such as chitosan, protamine, or a cationic lipid.

56. (Previously Presented) The wax-film composite of claim 33, wherein the wax-film composite is applied to an application site comprising: the skin, mouth, vagina, nasal cavity, or other accessible mucosal site.

57. (Previously Presented) The wax-film composite of claim 56, wherein the wax-film composite adheres to the application site for at least one hour.

58-62. (Canceled)

63. (New) The wax-film composite of claim 41, wherein the weight ratio of Noveon to Eudragit is from about 2:1 to about 4:1.

64. (New) The wax-film composite of claim 47, wherein the active pharmaceutical compound is an antimicrobial, an antiviral, an antiinflammatory, an antiseptic, an antihistamine, a local anesthetic, a disinfectant, a keratolytic, an analgesic, an anti-migraine or an anti-fungal.